Behavioral Scientist Participation in RCTs

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Purpose

- Why you should participate in RCTs
- Personal history/Lessons learned

Why Participate?

- Answers to applied questions are important
  - Evidence-based health practices are needed
  - Behavior is central to them
- Intellectual challenge
  - Study design
  - Study execution
- Variety and excitement

Research Series

- Behavioral Clinical Research
  - Monetary Incentives for Behavior Change
  - Behavioral Prescriptions and Behavior Change
- Behavioral Public Health Research
  - Mass Behavior Modification
  - Environmental Interventions
- Medical Outcomes Research
  - Hypertension
  - Diabetes

Challenge of Behavioral Obesity Interventions

- People want to lose weight
- Needed behavior changes are well known
- Achieving and maintaining change is difficult

Conceptual Model for Weight Control Failure

- Behavioral cost exceeds reward

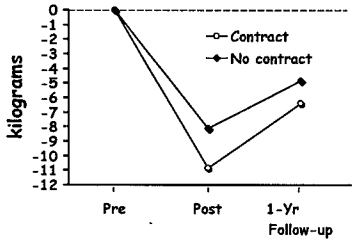
Intervention Solution

- Reduce cost
- Increase incentives

Monetary Contracts for Weight

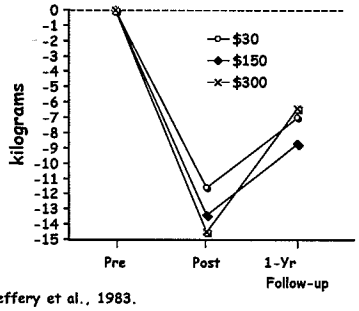
- **Principle:** Patient makes a motivational financial commitment prior to behavior change. Therapist makes sure that commitment is sustained over time.
- **Procedure:** Patient gives therapist money that is returned contingent on weight change.

Effects of Monetary Contracts on Weight



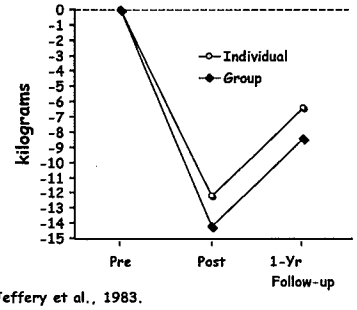
Jeffery et al., 1984.

Effects of Monetary Contract Size on Weight



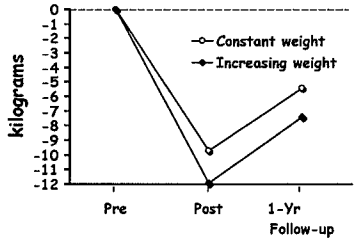
Jeffery et al., 1983.

Effects of Group versus Individual Monetary Contracts on Weight



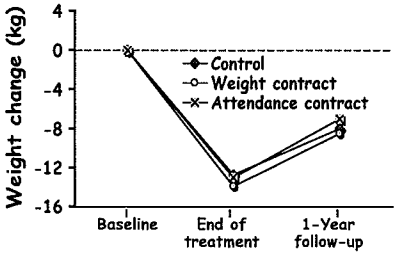
Jeffery et al., 1983.

Effects of Monetary Contract Payment Schedules on Weight



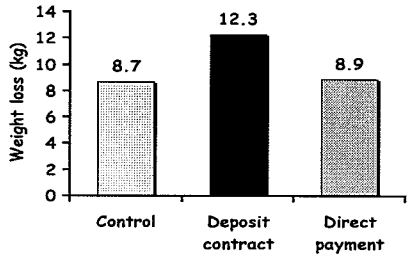
Jeffery et al., 1984.

Deposit Contracts in Long-Term Weight Loss

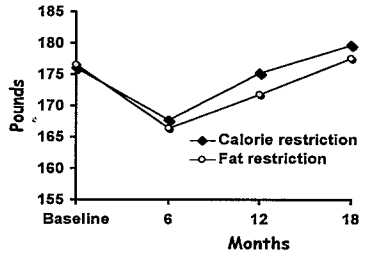


Kramer et al., 1986.

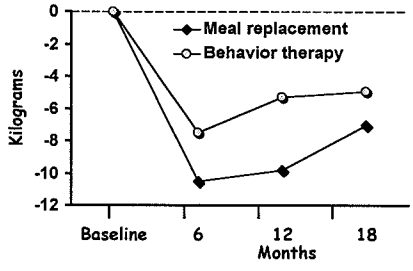
Weight losses at 6 months with direct payment and deposit contract incentives.



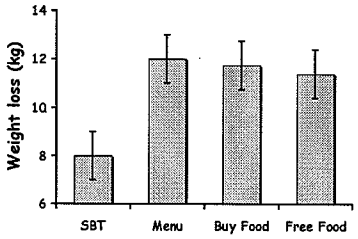
Weight change over 18 months in groups with calorie versus fat restricted diets.



Weight changes over 18 months with and without meal replacement.



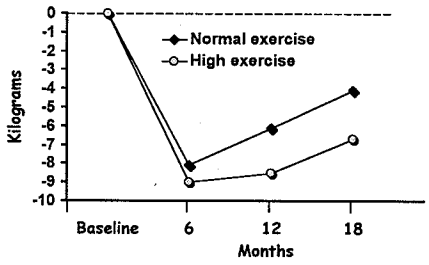
TRIM: Weight loss from baseline to 6 months for subjects in four treatment conditions.*



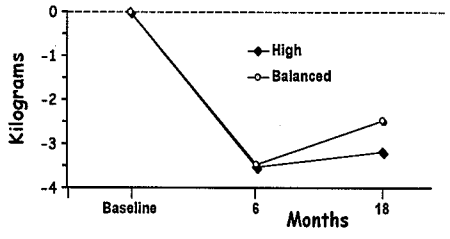
Wing et al., 1996.

* SBT: Standard Behavioral Treatment Condition
Menu: SBT + Meal Plans & Grocery Lists
Buy Food: SBT + Meal Plans + Food Provision, with cost sharing of food
Free Food: SBT + Meal Plans + Food Provision, with food provided free

Weight loss with high (2500 kcal/wk) and normal (1000 kcal/wk) exercise.



Weight loss with high and balanced outcome expectancies.



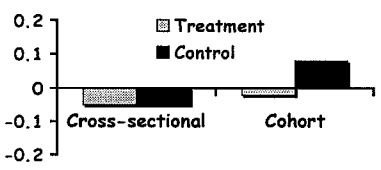
The Healthy Worker Project (HWP)

A randomized trial of worksite interventions for weight loss and smoking cessation

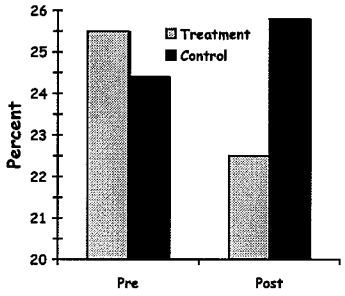
HWP Project Overview

- Thirty-two (32) worksites employing approximately 20,000 people
- Randomized to treatment or control
- Two years of intervention on weight and smoking
- Evaluation via cohort and cross-sectional surveys

Change in BMI from baseline to follow-up.



Healthy Worker Project Smoking Prevalence



Jeffery et al., 1993.

SUCCESS Project

Rationale: Can offering smoking cessation programs at work reduce population prevalence in proportion to levels of employee participation? Can different cessation format offerings or participation with monetary incentives increase participation and thus cessation rates?

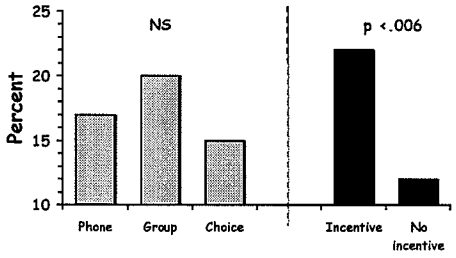
SUCCESS Project Design

Design:

- 2 X 3 factorial
- Monetary incentives for participation (Yes/No)
- Type of cessation program (group, phone, or both)

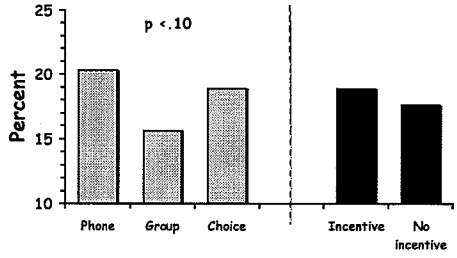
Group randomized trial with 24 worksites

SUCCESS: Percent participation in programs.



Hennrikus et al., 2002.

SUCCESS: Percent quitting smoking at 24 months.



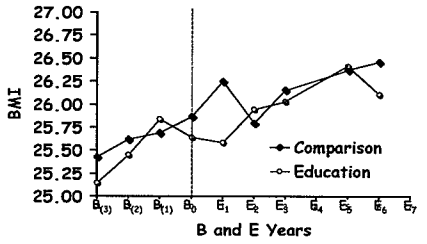
Minnesota Heart Health Program (MHHP)

A 10-year research and demonstration project to evaluate the effectiveness of multicomponent interventions to reduce CVD incidence and mortality.

Description of MHHP

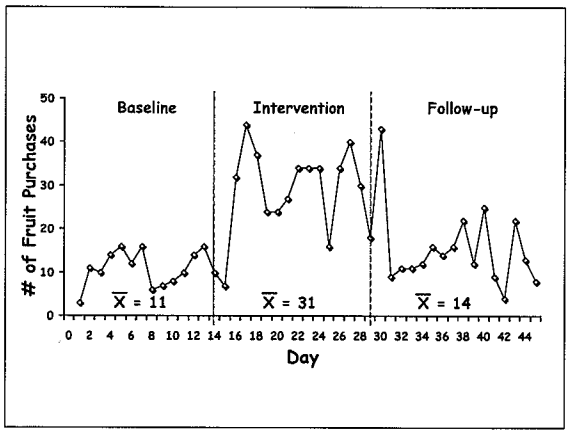
- Three matched community pairs
- Seven years of intervention including:
  - risk factor screening
  - mass media
  - adult education
  - worksite intervention
  - school intervention
  - restaurant intervention
  - etc.

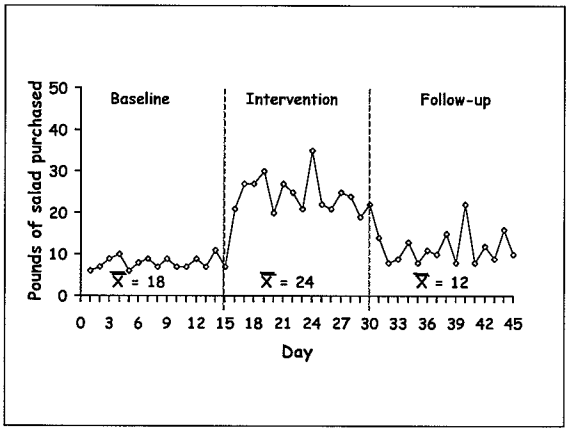
Mean BMI in MHHP education and comparison communities by year: Cross-sectional surveys.



Cafeteria Study of Price and Availability Influences on Fruit and Salad Consumption

- Three (3) weeks baseline observation
- Three (3) weeks interventions
  - 50% price reduction
  - increased choices
- Three (3) weeks return to baseline

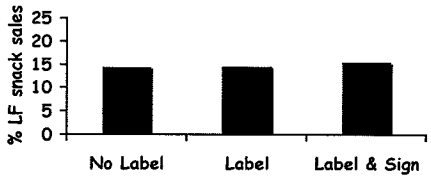




CHIPS

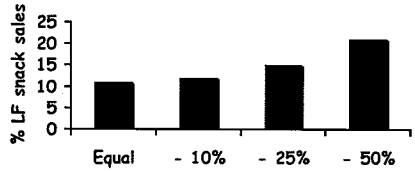
- Randomized trial with Latin Squares design studying effects of price and health education on vending machine snack choices.
- 12 worksites and 12 high schools
- Health education:
  - None
  - Fat color codes
  - Fat color codes + promotional ads
- Pricing:
  - Equal
  - Low-fat discount of 10%, 25%, 50%

Effect of Health Promotion on Low-Fat Snack Sales



% increase in sales: 1% 8%

Effect of Price on Low-Fat Snack Sales

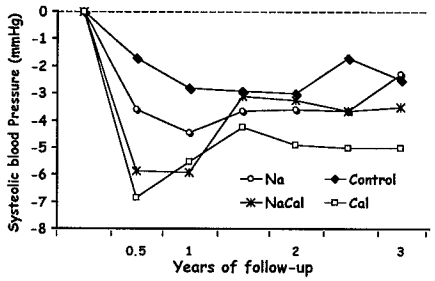


% increase in sales: 9% 39% 93%

Hypertension Prevention Trial Design

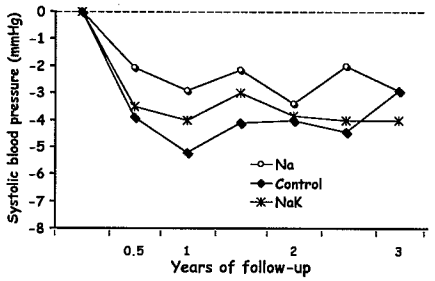
- Subjects with elevated blood pressure
- If overweight, randomized to:
  - Control
  - Weight loss
  - Weight loss + Sodium decrease
  - Sodium decrease
- If not overweight, randomized to:
  - Control
  - Sodium decrease
  - Sodium decrease + Potassium increase
- Three year follow-up

Systolic changes during follow-up in blood pressure by study component and treatment group: Overweight participants



Hypertension Prevention Trial Research Group, 1990.

Changes during follow-up in systolic blood pressure by study component and treatment group: Normal weight participants



Hypertension Prevention Trial Research Group, 1990.

Look AHEAD Design

- **Subjects**
  - Age 45-74
  - BMI ≥ 25.0
  - Type 2 diabetes melitus
- **Treatments**
  - Behavioral weight loss
  - Diabetes education control
- **Follow-up:** 10 years

Challenges of Behavioral RCTs

- Variability of intervention effects
- Avoiding bias due to knowledge of treatment group assignment
  - intervention efficacy
  - outcome assessment
- Dropout and missing data
- Decision making by committee can stifle innovation
- Size reduces quality
- Maintaining consistency across sites/staff & time
- Waiting years for study results

Bottom Line

- Behavioral science involvement in RCTs is very important.
- Many of the most promising potentials for improvement of human health are behavioral.
- A better evidence base for deciding how to address these issues is critical.
- RCTs are a major method for acquiring this evidence.
- RCTs are a fun and fulfilling research career.

Weigh-To-Be (WTB)

Randomized trial evaluating phone- and mail-based weight-loss interventions in an HMO.

Description of WTB

- Randomization of 1801 adults to:
  - usual care
  - mail treatment
  - phone treatment
- Evaluation at 6-month intervals for 2 years.

Weight Loss by Treatment Group